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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/780,484	02/17/2004	David B. Rozema	Mirus.030.16.04	2135
<div>7590 Mark K. Johnson Mirus Corporation 505 S. Rosa Rd. Madison, WI 53719</div>			<div>EXAMINER EPPS FORD, JANET L</div>	
			<div>ART UNIT 1633</div>	<div>PAPER NUMBER</div>
			<div>MAIL DATE 07/10/2008</div>	<div>DELIVERY MODE PAPER</div>

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/780,484	<b>Applicant(s)</b> ROZEMA ET AL.	
	<b>Examiner</b> Janet L. Epps-Ford	<b>Art Unit</b> 1633	

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 4-28-08.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-7 and 10-20 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1,3-7 and 10-20 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)          | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____                                      |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)          | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____  | 6) <input type="checkbox"/> Other: _____                          |

***DETAILED ACTION***

***Continued Examination Under 37 CFR 1.114***

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office Action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed 4-21-08 has been entered.
2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.
3. Claims 1, 3-7, and 10-20 are presently pending.

***Response to Arguments***

***Claim Rejections - 35 USC § 102***

4. Claims 1, 3-7, 10-16 and 19-20 remain rejected under 35 U.S.C. 102(e or a) as being anticipated by Pinchuk et al. (US 2002/0107330), for the reasons of record.
5. Applicant's arguments filed 4-28-08 have been fully considered but they are not persuasive.
6. Applicants traversed the instant rejection by way of amending the claims to recite "wherein cleavage of the functional groups restores the amines of the polyamine." However, contrary to Applicant's assertions, the term "cleavage" as recited in the claims as amended is not limited to merely exposure of the pH labile bond to a change in pH.

The term "cleavage" can encompass any conditions which would promote removal of the functional groups, such that reversal of the modification must restore the amine.

7. Furthermore, it is noted that Applicants have not addressed the following arguments presented by the examiner in the prior Office Action, these arguments are reproduced below:

8. Moreover, Applicant's have provided a description of what Applicant believes is the mechanism by which S-nitroso-thiol modifications function to attach functional groups to the disclosed polymers (which includes polyvinyl ether). Applicant's description is not representative of the full scope of possible mechanisms by which the S-nitrothiol groups can function to release therapeutic groups with oppositely charged functional groups from modified polyamines. Contrary to Applicant's assertions and absent evidence to the contrary, the polyvinyl ether polymers comprising the thiol based modifications taught by Pinchuk et al. read on the pH labile modifications recited in the instant claims.

9. Claims 1, 3-5, 7, 10-15, 17, and 19-20 remain rejected under 35 U.S.C. 102(b) as being anticipated by Wolff et al. (US 20010036926), for the reasons of record; Claims 1, 3-5, 7-15, 17 and 19-20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wolff et al. (US 7,087,770), for the reasons of record; Claims 1, 3-5, 7, 10-15 and 17-20 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Wolff et al. in view of Blazyk (WO 200160162 A2; see disclosure of US 20040249122 A1); and Claim 18 remains rejected on the ground of nonstatutory obvious-type double patenting as being unpatentable over Wolff et al. in view of Blazyk (WO 200160162 A2), for the reasons

given above, and in the rejection under 35 USC 103(a) over Wolff et al. in view of Blazyk.

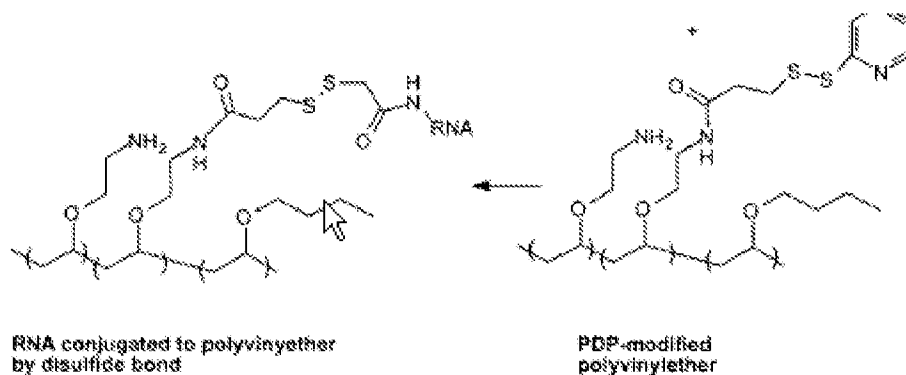
10. Applicant's arguments filed 4-21-08 have been fully considered but they are not persuasive.

11. Applicants traversed the instant rejection by way of amending the claims to recite "wherein **cleavage** of the functional groups restores the amines of the polyamine." However, contrary to Applicant's assertions, the term "cleavage" as recited in the claims as amended is not limited to merely exposure of the pH labile bond to a change in pH. The term "cleavage" can encompass any conditions which would promote removal of the functional groups, such that reversal of the modification must restore the amine.

12. Furthermore, it is noted that Applicants have not addressed the following arguments presented by the examiner in the prior Office Action, these arguments are reproduced below:

13. Contrary to Applicant's assertions, as stated in the prior Office action, Wolff et al. teach that "[t]he monomers used for polymerization can also contain chemical moieties that can be modified before or after the polymerization including (but not limited to) amines (primary, secondary, and tertiary), amides, carboxylic acid, ester, hydroxyl, hydrazine, alkyl halide, aldehyde, and ketone. (see paragraph [0103]). Polyethyleneimine and polylysine were used in specific examples to form complexes with nucleic acid via a disulfide linkage, see examples 4 and 5. Therefore, contrary to Applicant's assertions, the teachings of Wolff et al. read on the instant claims as amended.

14. Moreover, Applicant's own specification at Figure 3, describes what Applicants consider to be the reversible modification of a polyvinylether amine:



It is clear that Applicants contemplated the use of the modification which incorporate a disulfide linkage within the scope of the reversible modifications encompassed by the instant claims.

### ***Double Patenting***

15. The rejection of claims 1-5, 7-15, 17 and 19-20 on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-7 of U.S. Patent No. 7,087,770, is withdrawn.

### ***Claim Rejections - 35 USC § 102***

16. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

17. Claims 1, 3-7, and 10-13 rejected under 35 U.S.C. 102(e) as being anticipated by Rozema et al. (US Patent NO. 7,019,113)

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Rozema et al. teach the formation of an oligonucleotide-polycation complex by the reaction an amine modified morpholino polynucleotide with CDM-thioester and then adding the modified oligonucleotide to polyethylenimine-Cys, see col. 14, last ¶. See Also col. 15-16. Absent evidence to the contrary this disclosure of Rozema et al. read on the compositions of the instant invention.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Janet L. Epps-Ford whose telephone number is 571-272-0757. The examiner can normally be reached on M-F, 10:00 AM through 6:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on 571-272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Janet L. Epps-Ford/  
Primary Examiner, Art Unit 1633